IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE

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DONALD MILLER, On Behalf of himself and Others Similarly Situated,

Plaintiff,

vs.

Civil Action No. 05-2113-Ma An

PFIZER, INC., WARNER-LAMBERT COMPANY, LLC and PARKE-DAVIS, & COMPANY, a Division of WARNER-LAMBERT COMPANY,

Defendants.

NOTICE OF REMOVAL

PLEASE TAKE NOTICE that pursuant to 28 U.S.C. § 1441, et seq., Defendants Pfizer Inc., Warner-Lambert Company LLC, Parke-Davis & Company, a Division of Warner-Lambert Company (collectively, "Defendants") hereby remove the above-entitled action from the Circuit Court of Shelby County, Tennessee to the United States District Court for the Western District of Tennessee. This Court has removal jurisdiction because this is a civil action "of which the district courts have original jurisdiction" and it is an action "founded on a claim or right arising under . . . the laws of the United States." 28 U.S.C. § 1441(a)-(b); *see* 28 U.S.C. § 1331. In further support of this Notice of Removal, Defendants allege as follows:

1. On January 6, 2005, Plaintiff filed a class action complaint entitled Donald Miller, on behalf of himself and all others similarly situated v. Pfizer, Inc., Warner-

Lambert Company, LLC and Parke-Davis & Company, a division of Warner-Lambert Company, Civil No. CT-00009605 in the Circuit Court of Shelby County, Tennessee. The complaint was served on Defendants on January 12, 2005

2. Pursuant to 28 U.S.C. § 1446(a), true and correct copies of all process or pleadings served upon those Defendants prior to the filing of this Notice of Removal are attached as Exhibit A to this Notice of Removal.

3. The Defendants were served with the original Complaint on January 12, 2005. Accordingly, this Notice of Removal is timely under 28 U.S.C. § 1446(b) because it is filed within 30 days after the Defendants were served with the Complaint and because all Defendants consent to removal.

4. Pursuant to 28 U.S.C. § 1446(b), the Defendants have filed a copy of this Notice of Removal with the Clerk of Court for the Circuit Court of Shelby County, Tennessee. Defendants have also served plaintiffs with a copy of this Notice of Removal.

ALLEGATIONS OF THE COMPLAINT

5. Plaintiff's Complaint alleges that Defendants illegally promoted Neurontin and instructed medical liaisons to market and sell Neurontin in violation of federal law. Compl. ¶¶ 2, 17-18, 28. Plaintiff asserts that the Food and Drug Administration ("FDA") in 1993 approved Neurontin as an "adjunctive therapy" for epilepsy. ¶ 14. The FDA approved the drug for use as an adjunct to other medications designed to treat epilepsy and established a dosage range at which it could be administered to patients. *See Id.*

6. Plaintiff alleges that the FDA's approval of Neurontin as adjunctive therapy for epilepsy thereby limited the drug's marketing and promotion for so-called

"off label" uses. The Federal Food, Drug, and Cosmetic Act, 21 U.S. C. §301, et seq., prohibits marketing drugs for "off-label" uses. Compl. ¶ 17. "Manufacturers of prescription medications are prohibited from promoting and/or marketing the use of medications for purposes or in dosages other than those approved by the FDA." *Id.* Plaintiff asserts that after Neurontin was approved by the FDA, Defendants allegedly violated FDA regulations by marketing the drug for other uses. Compl. ¶¶ 21, 26, 28. According to the Complaint, Neurontin was promoted for treatment of pain, so-called monotherapy for epilepsy, bipolar disorder and attention deficit disorder. Compl. ¶ 34. Plaintiff was prescribed Neurontin "for nerve damage resulting from a neck operation in approximately March 2004." Compl. ¶ 81. Plaintiff alleges that he and others "have suffered losses through payments, deductibles, and other out-of-pocket expenses for Neurontin prescriptions for 'off-label,' non-FDA approved and/or medically unnecessary uses." Compl. ¶83.

7. Defendants are alleged to have constructed a scheme that violated the FDCA and FDA regulations governing off-label use. Compl. ¶ 2-3. Specifically, Plaintiff alleges that Defendants "channeled payments to physician investigators;" employed "medical liaisons" to directly solicit doctors to prescribe the drug for off-label uses; engaged in "fraudulent marketing strategy;" used an "improper marketing and sales scheme;" and "knowingly and willfully facilitated, communicated and distributed misrepresentations concerning the efficacy of Neurontin for off-label uses." Compl. ¶ 50, 59, 60.

8. At bottom, the Complaint establishes that the acceptable parameters for marketing Neurontin were established by the FDA: "Defendants scheme to promote

'off-label' uses of Neurontin was designed to avoid the FDA's normal regulatory process pertaining to the marketing of a new use of a drug, and to actively conceal the illegal means by which it marketed the drug." Compl. ¶ 2. Plaintiff alleges that Defendants filed their New Drug Application ("NDA") with the FDA and patents relative to the treatment of depression, neurogenerative disease, mania , bipolar disease, anxiety and panic attacks. "Notwithstanding the claims made in these patents, Defendants never sought FDA approval for the use of Neurontin to treat the conditions described therein." Compl. ¶ 16.

9. At the same time, Plaintiff claims that Defendants' alleged conduct violates the Tennessee Consumer Protection Act of 1977, Tenn. Code Ann. § 47-18-101, et seq. In addition, the Complaint alleges that Defendants, in their marketing of Neurontin, were negligent or grossly negligent, and breached the implied warranty of merchantability. Compl. ¶¶ 1, 79-80,82, 85. Further, Plaintiff alleges that Defendants intentionally concealed their actions, thereby tolling any applicable statutes of limitation. Compl. ¶¶ 74, 76-77.

JURISDICTION

10. This Court has removal jurisdiction because this is a civil action "of which the district courts have original jurisdiction" and an action "founded on a claim or right arising under . . . the laws of the United States." 28 U.S.C. § 1441 (a), (b); *see* 28 U.S.C. § 1331.

11. Federal question jurisdiction exists in this action because Plaintiff's state law claims are not only inextricably intertwined with, but also arise from, violations of federal statutes and regulations.

12. The interpretation of the federal statutes and regulations regarding the promotion of pharmaceutical drugs is a substantial question that is pivotal to the resolution of Plaintiff's state-law claims. The resolution of Plaintiff's allegations necessarily turns on the construction of federal law, namely whether Defendants violated the FDCA or the regulations of the FDA. *See* Franchise Tax Bd. v. Constr. Laborers Vacation Trust, 463 U.S. 1, 28 (1983) (holding that federal question jurisdiction exists whenever "the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law"); City of Chicago v. Int'l Coll. of Surgeons, Inc., 522 U.S. 156, 164 (1997) ("[E]ven though state law creates [a party's] causes of action, its case might still 'arise under' the laws of the United States if a well-pleaded complaint established that its right to relief under state law requires resolution of a substantial question of federal law." (internal quotation marks omitted)). Indeed, it will not be possible to determine whether Plaintiff may prevail on his state law claims without first resolving these intricate issues of federal law.

13. The conduct that Plaintiff complains of, including "direct solicitation of physicians for off-label uses" and the use of "medical liaisons," may be deemed wrongful only so far as it runs counter to FDA regulations. Compl. ¶ 28, 37. The gravaman of the Complaint, thus, is Defendants' alleged failure to conform its actions to federal law. Despite Plaintiff's attempt to disclaim this Court's subject matter jurisdiction, a substantial federal question unmistakably resides at the heart of this action.

14. Because Plaintiff's claims rely upon the interpretation and application of the FDCA and the FDA's regulations, and given that a plaintiff may not defeat removal by failing to plead necessary federal questions, federal court is the proper forum for addressing these claims. Further, the need for uniform interpretation and enforcement of the FDCA and the FDA's own regulations, underscores the appropriateness of removal of this action.

15. Moreover, because a case is properly removable if it could have been filed in the first instance in federal court, it is significant that lawsuits grounded upon the same set of facts as those alleged here have, in fact, already been filed in federal courts across the country. Lawsuits containing nearly identical allegations as those found here, including nationwide classes, which subsume the class described in Plaintiff's Complaint, have been consolidated for pretrial coordination and proceedings in a Multidistrict Litigation Court ("MDL"). *See* In re Neurontin Marketing and Sales Practices Litigation, Docket No. 1629. At latest count, 27 actions from sixteen separate U. S. District Court districts were consolidated before Judge Saris of the District of Massachusetts, with Conditional Transfer Orders assigning an additional 24 "tag-along" actions for transfer to the MDL.

INTRADISTRICT ASSIGNMENT

16. Pursuant to 28 U.S.C. § 1446(a), venue of this action is proper in this Court as the division within which the state court action was brought.

WHEREFORE, Defendants Pfizer Inc, Parke-Davis and Warner-Lambert Company notice removal of this case to the United States District Court for the Western District of Tennessee.

Respectfully submitted,

STOKES BARTHOLOMEW EVANS & PETREE, P.A.

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was served upon B. J. Wade, Esq. and Russell A. Wood, Esq., 26 North Second Street, Memphis, Tennessee 38103, via regular U.S. Mail, postage prepaid, this 8th day of February, 2005.

IN THE CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL DISTRICT AT MEMPHIS

FILED
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CIRCUIT COURT CLERK
BY _____ D.C.

DONALD MILLER, On Behalf of himself and Others Similarly Situated, 108094

Plaintiff,

vs.

Docket No.: CT-000096-05
CLASS ACTION
JURY DEMANDED

PFIZER, INC., WARNER-LAMBERT COMPANY, LLC and PARKE, DAVIS & COMPANY, a Division of WARNER-LAMBERT COMPANY,

Defendants.

PLAINTIFF'S ORIGINAL CLASS ACTION COMPLAINT

Plaintiff, Donald Miller, on behalf of himself and all others similarly situated by and through his undersigned counsel, Glassman, Edwards, Wade & Wyatt, P.C., and based on information and belief except for his own acts and beliefs, which are based upon personal knowledge, states as follows:

NATURE OF THE ACTION

1. This class action is brought by Plaintiff, a direct payor, to recover payments he has made for the drug Neurontin® ("Neurontin"), an epilepsy drug manufactured, marketed, and sold by defendants Pfizer, Inc., Warner-Lambert Company and Parke-Davis, a division of the Warner-Lambert Company (collectively "Defendants"). On behalf of himself and all others similarly situated, Plaintiff asserts claims against Defendants for violations of the Tennessee Consumer Protection Act, § 47-18-101, *et seq.*, breach of implied warranties, and unjust enrichment.

EXHIBIT A

2. Although Neurontin was approved by the United States Food and Drug Administration (the "FDA") only as an "adjunctive therapy" for epilepsy, Defendants embarked on a scheme in 1994 to promote Neurontin for "off-label" uses for which the drug had not received FDA approval. Defendants recognized a gargantuan profit potential in the "off-label" promotion of Neurontin to treat other diseases and at higher dosages. By convincing health care providers, including doctors and hospitals, to prescribe Neurontin, it would enrich Defendants by billions of dollars. Defendants' scheme to promote "off-label" uses of Neurontin was designed to avoid the FDA's normal regulatory process pertaining to the marketing of a new use of a drug, and to actively conceal the illegal means by which it marketed the drug.

3. Defendants, along with other entities and individuals, created an illegal scheme to cause patients and their third-party payors to pay for "off-label" uses of Neurontin that were not safe or medically efficacious. Defendants knew there was no scientific basis to support such off-label uses. Defendants' scheme targeted third-party payors, health insurers, patients and others, specifically to increase the market for Neurontin and, consequently, Defendants' revenues by billions of dollars.

4. Defendants' improper marketing and sales practices included, *inter alia*:

- kickbacks to physicians who prescribed large amounts of Neurontin for "off-label" purposes to patients whose prescriptions were paid by indivduals such as Plaintiff;
- the formation of a nationwide network of employees, falsely referred to as "medical liaisons," whose assigned duties consisted entirely of direct sales activities without any legitimate scientific activity;
- the illegal direct solicitation of physicians for "off-label" uses;
- false statements to physicians and pharmacists concerning the efficacy and safety of Neurontin for "off-label" uses;
- instructing doctors and pharmacists how to conceal and misrepresent the use of Neurontin for off-label uses on claim forms submitted to third-party payors;

- causing doctors and pharmacists to submit claim forms to third-party payors, misinforming them about Neurontin;

- publishing articles, studies and reports that intentionally misrepresented the medical efficacy of Neurontin for off-label uses;

- intentionally misrepresenting and concealing Defendants' role in the creation and sponsorship of articles and publications aimed to sell Neurontin to off-label markets; and

- actively training Parke-Davis employees how to avoid detection of their activities by governmental agencies and endpayors.

5. As a result of their scheme, Defendants exponentially increased the sales of and market for Neurontin based on misrepresentations, concealment and false scientific data. For example, Parke-Davis's worldwide revenues from Neurontin sales totaled $292 million in 1997; $913 million in 1999; $1 billion in 2000; $2 billion in 2002; and $2.7 billion in 2003. Similarly, the off-label use of Neurontin increased from 50% of Neurontin's sales in 1996, to more than 78% in 2000, and 94% in 2002. Fueled by increased off-label uses, sales of Neurontin continue to grow each year.

JURISDICTION AND VENUE

6. This Court also has jurisdiction pursuant to Rule 23 of the Tennessee Rules of Civil Procedure.

7. This Court has subject matter jurisdiction over this class action and the Defendants in this action because Plaintiff and members of the Class were prescribed and indeed paid for Neurontin in Shelby County, Tennessee. Moreover, Defendants systematically and continually conducted business in Shelby County, Tennessee, and all or part of its transactions which give rise to this action took place in the State of Tennessee. .

8. Venue is proper in Shelby County pursuant to Tennessee Code Annotated § 47-18-109(a) because Defendants conduct business in this County.

9. Defendants conduct business in Shelby County through marketing, advertising, and sales directed to Tennessee residents. Further, at all times mentioned in this Complaint, Defendants, directly and through their agents, made misrepresentations and material omissions to residents of Shelby County, including Plaintiff, and residents of the State of Tennessee. Neurontin was prescribed and paid for by certain class plaintiffs in Shelby County.

10. Plaintiff and Class members do not assert any federal claims or federal questions in the prosecution of this matter and no member of the Class suffered damages in excess of $74,999.00.

PARTIES

11. Plaintiff Don Miller resides at 1312 Locke-Cuba Road, Millington, TN 38053. Plaintiff paid for off-label, non-FDA approved and/or medically unnecessary, unsafe, or unefficacious uses of Neurontin as a result of Defendant's deceptive practices.

12. Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York. Pfizer is registered with the State of Tennessee as a foreign for profit corporation in good standing with its registered agent listed as The Corporation Company, 425 West Capitol Ave., Ste. 1700, Little Rock, AR 72201. Pfizer is principally engaged in the manufacture and sale of pharmaceuticals and is one of the largest pharmaceutical companies in the United States.

13. Defendant Warner-Lambert Company, LLC ("Warner-Lambert") was acquired in June 2000 by Pfizer and is now a wholly-owned subsidiary of Pfizer. This acquisition included Warner-Lambert's Parke-Davis division. As a result of the acquisition, Pfizer is responsible for all liabilities resulting from any wrongful acts or omissions of Parke-Davis or Warner-Lambert that occurred prior to the Warner-Lambert acquisition. Prior to the acquisition, Warner-Lambert was a Delaware corporation that maintained its principal place of business at 201 Gabor Road, Morris

Plains, New Jersey. In 1993, Warner-Lambert received FDA approval to market Neurontin in the United States and did so through its Parke-Davis division.

FACTUAL ALLEGATIONS

Defendants' Non-FDA-Approved "Off-Label" Marketing Scheme

14. The FDA approved Neurontin in 1993 for use as an "adjunctive therapy" for epilepsy in doses from 900 to 1800 milligrams per day. Neurontin's approval as an adjunctive therapy meant that the drug could not be prescribed by itself for the treatment of epilepsy, but rather, only as an add-on drug in the event that a primary anti-epilepsy drug was not successful.

15. At the time Neurontin was approved, Defendants' original patent on Neurontin was scheduled to expire in December 1998. This left Defendants with only a small window of exclusivity for this drug. After the expiration of the Neurontin patent, Defendants would be forced to share the market with generic drug manufacturers, substantially reducing their profits and their ability to keep Neurontin's retail price at supra-competitive levels.

16. When Defendants filed their New Drug Application ("NDA") with the FDA, Defendants intended Neurontin to be used for other purposes or "indications" besides epilepsy adjunctive therapy. In October 1990, Defendants filed a patent for Neurontin claiming it to be effective in the treatment of depression. In November 1990, Defendants filed another patent application for Neurontin claiming it to be effective for the treatment of neurogenerative disease. In 1995, Defendants filed additional patent applications for mania and bipolar disease, as well as for anxiety and panic attacks. Notwithstanding the claims made in these patents, Defendants never sought FDA approval for the use of Neurontin to treat the conditions described therein.

17. New pharmaceutical drugs may not be marketed in the United States until the drug's sponsor proves to the FDA that the drug is safe and effective for specific indications at specified

dosages. The FDA-approved indication and dosage level are set forth on the drug's labeling. Uses of a prescription drug for purposes or at dosages other than those approved by the FDA are referred to as "off-label" uses. Although it is not unlawful for physicians to prescribe approved drugs for off-label uses, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301, *et seq*., strictly prohibits drug companies from marketing drugs for uses other than those set forth in the drug's approved labeling.

18. The market for adjunctive therapy for treating epilepsy is relatively small, with an affected population of only two million patients. To broaden its market, Defendants began illegally promoting Neurontin to physicians for at least eleven off-label uses, including pain management, psychiatric disorders, anxiety, and depression. In fact, by the late 1990s, Neurontin was commonly referred to as the "snake oil" drug.

19. Initially, Defendants planned to file supplemental NDAs to expand Neurontin's approved indications, including monotherapy (which would permit Neurontin to be prescribed by itself for epilepsy treatment) and for various psychiatric and neurological indications. By 1995, Parke-Davis recognized it would be uneconomical to assume the expense and time necessary to conduct the clinical trials to prove that Neurontin was safe and effective for these uses. Assuming Neurontin would be proven to be safe and effective, the near-term expiration of the patent meant that generic manufacturers of Neurontin would reap much of the reward that comes with proving Neurontin could be safely used for other indications. Defendants decided not to file the NDAs.

20. Instead, Defendants designed and employed a variety of fraudulent practices to convince physicians of the safety and medical efficacy of Neurontin, to incentivize and reward them for prescribing the drug.

21. Although federal regulations prohibited Defendants from promoting Neurontin for

FDA non-approved uses, drug manufacturers are permitted to disseminate publications by independent third parties that describe the effects of off-label uses, provided that they do so only in response to non-solicited requests from physicians. To exploit this loophole, Defendants employed "medical liaisons" to market Neurontin and distribute medical literature that was created by Defendants to physicians. In so doing, Defendants avoided using regular sales staff to market Neurontin's off-label uses.

22. As part of Defendants' scheme, they surreptitiously hired non-physician technical writers to write articles for medical journals. Defendants reviewed and approved these articles, and then paid physicians to lend their names as the articles' "authors." Defendants retained outside firms to broker these articles to various medical journals to create the illusion that Defendants did not create and sponsor the articles themselves. This aspect of Defendants' scheme is illustrated by a December 1996 proposal to Parke-Davis from a Philadelphia company called Medical Education Systems ("MES"). In the proposal, MES requested $160,000 to develop a series of 12 scientific articles to "support epilepsy education." In fact, three of the proposed articles related specifically to Neurontin and bipolar disorder. Additionally, Parke-Davis carefully controlled the articles' content in order to promote Neurontin's "off-label" uses – it approved the authors and topics; it cleared the journals in which the articles were printed; and its executives edited the articles' drafts.

23. Defendants rewarded physicians for prescribing or advocating Neurontin for off-label uses by making payments under the guise of "consulting" arrangements, medical education seminars, grants, and "studies," requiring virtually nothing from the physicians.

24. To ensure that third-party payors covered and paid for the drug, Defendants instructed and assisted pharmacists and others on how to misrepresent the use of Neurontin in claims submitted to third-party payors.

25. Defendants' scheme caused Plaintiff to pay for Neurontin prescription claims for off-label uses.

Defendants' Employment of Medical Liaisons to Promote Off-Label Uses

26. The FDA permits drug company representatives to provide balanced, truthful information regarding "off-label" uses if specifically requested by a physician without first being solicited by the drug company. In 1995, Defendants hired and trained medical liaisons to aggressively solicit physician requests for off-label information. Defendants instructed the liaisons to promote Neurontin's off-label uses with non-scientific, anecdotal information of Neurontin. Whereas medical liaisons are ordinarily connected to the research divisions of the manufacturer, Parke-Davis's liaisons were employed exclusively as sales and promotion personnel. Defendants knew this use of medical liaisons was inappropriate. High-level personnel employed by Defendants have acknowledged that it was a thinly disguised method of violating the FDA's policies concerning off-label promotion.

27. On April 16, 1996, at a training session for medical liaisons, Defendants' in-house lawyers stopped the video recorder to advise the liaisons off camera that notwithstanding formal policies to the contrary, they were permitted to cold-call physicians as long as they executed request forms (forms verifying physician initiation) at the end of the call. Moreover, the request forms could be filled out by Defendants' sales representatives instead of the doctors. Company lawyers also stated that the liaisons need not present balanced information to the customers, reminding them that sales were necessary to keep the company profitable. The liaisons were also informed, off-camera, that the term "solicitation" was ambiguous and methods existed to induce physician inquiries. The lawyers warned the liaisons that any information about off-label uses should not be put in writing.

28. Defendants specifically instructed medical liaisons to market and sell Neurontin for off-label uses. During a teleconference on May 24, 1996, John Ford, a senior marketing executive at Parke-Davis's Morris Plains headquarters, directly instructed medical liaisons to market Neurontin for monotherapy, pain, bipolar disease, and other psychiatric uses. At another meeting, Ford stated:

> I want you out there every day selling Neurontin. Look this isn't just me, it's come down from Morris Plains that Neurontin is more profitable.... We all know Neurontin's not growing adjunctive therapy, beside[s] that is not where the money is. Pain management, now that's money. Monotherapy, that's money. We don't want to share these patients with everybody, we want them on Neurontin only. We want their whole drug budget, not a quarter, not half, the whole thing.... We can't wait for them to ask, we need to get out there and tell them up front.... That's where we need to be holding their hand and whispering in their ear "Neurontin for pain, Neurontin for monotherapy, Neurontin for bipolar, Neurontin for everything...." I don't want to see a single patient coming off Neurontin until they have been up to at least 4800 mg/day. I don't want to hear that safety crap either, have you tried Neurontin, every one of you should take one just to see there is nothing, it's a great drug.

29. Misrepresentations about the status of medical liaisons were an important part of Defendants' illicit marketing scheme. With the full approval of Defendants' marketing officials, including John Ford, Phil Magistro and John Krukar, medical liaisons were routinely introduced as specialists in the specific drug they were presenting at a particular meeting. Medical liaisons were presented as experts in anti-epileptic drugs at one presentation and experts in cardiac medication at another. Medical liaisons were encouraged to represent themselves as medical researchers, even though they neither conducted medical research nor analyzed medical research performed by others. It was common for medical liaisons to be introduced as physicians, even when they were not. Sales personnel were instructed to introduce medical liaisons as scientists and clinicians on leave from their academic duties to make special presentations to the physician; the fact that the liaisons were part of Defendants' standard marketing team was concealed.

30. Parke-Davis employees instructed medical liaisons on the how-to's of presenting "The Neurontin Cold-Call Story" to a neurologist, general practitioner, or psychiatrist for an off-label use:

- Say you are the eyes and ears of Parke-Davis research and you are gathering clinical information;
- Ask general questions about the nature of physician's practice;
- Mention Neurontin and its approved uses, but quickly dismiss them as old news;
- Ask leading questions about how many of their patients complain of pain;
- Ascertain the practice profile for all of the potential "off-label" uses;
- Reveal that Parke-Davis "has a great deal of information about the fantastic response rate of patients on Neurontin in all of these disease states";
- Discuss the clinical trials that this information is demanding;
- Highlight the "90-95% response rate that we are seeing in more than 80% of patients";
- Present the physician with available publications and emphasize that drugs for pain treatment are rarely featured in publications;
- Ask the physician to place some patients on Neurontin and say you will stay in touch to help develop case reports;
- Mention that case reports can be lucrative and lead to clinical trials;
- Offer to do a presentation and luncheon for the entire practice or a group of his friends to detail all of the "data" we have;
- Invite the physician to attend future consultant meetings and indicate that he will be compensated $250 plus a nice trip or meal in the city; and
- Close by recommending that the next patient he sees should be prescribed Neurontin.

31. Defendants instructed medical liaisons to coach doctors on how to conceal the off-label nature of any Neurontin prescription to obtain third-party reimbursement.

32. Defendants concealed their activities by shredding documents, falsifying documents and encouraging medical liaisons to conduct their marketing activities without leaving a "paper trail."

33. Defendants misrepresented the scientific support for off-label usage of Neurontin. A group of Defendants' executives called the "New Products Committee" decided to fund clinical trials on a variety of Neurontin uses, including treatment of bipolar disorder, social phobia, migraine and chronic pain, and then publicize the results through medical journals and medical conventions. The head of this committee was the then-president of Parke-Davis, Tony Wild.

34. Defendants publicized these clinical trial results but concealed evidence showing that Neurontin was not effective for these off-label conditions. The following misrepresentations were routinely made to physicians and other customer business units with the knowledge and consent of persons such as Phil Magistro, John Krukar, and other of Defendants' marketing personnel:

- **Bipolar Disorder**: Medical Liaisons falsely reported that early test results regarding treatment of bipolar disorder indicated a 90% response rate when the patient started with a 900 mg/day dosage and later increased to 4800 mg per day. However, ***no clinical trial was being conducted*** other than a pilot study. Moreover, Defendants' data did not show any response difference between 600 mg, 1200 mg and 2400 mg/day. Most of the published reports on this topic were written and sponsored by Defendants, but this fact was concealed. Medical liaisons were trained to misinform psychiatrists that there were no reports of adverse effect, even though personnel were aware of such reports at the time.

- **Peripheral Neuropathy, Diabetic Neuropathy, and Other Pain Syndromes**: Medical liaisons were trained and instructed to report that "leaks" from clinical trials demonstrated that patients with various pain syndromes had a 90% favorable response rate to Neurontin treatment. However, there was no legitimate proof of such response rate. Medical liaisons were trained to claim they had this knowledge from inside information about the clinical trials. In actuality, the only support for these claims was anecdotal evidence of nominal scientific value. As discussed below, many of the published case reports were created and/or sponsored by Defendants without acknowledgement of Defendants' involvement.

- **Epilepsy Monotherapy**: Medical liaisons were trained to inform neurologists that substantial evidence supported Neurontin's efficacy as monotherapy. Yet,

Defendants knew that clinical trials were inconclusive. One of Defendants' clinical trials, No. 945-82, showed that Neurontin was not an effective monotherapy agent; the vast majority of epilepsy patients in the study were unable to continue with Neurontin alone. The same study revealed no effective difference between administration of Neurontin at 600, 1200 or 2400 mg/day. Nevertheless, Defendants continued to claim that physicians should prescribe Neurontin at substantially higher doses than indicated on the label. In 1997, the FDA refused to find Neurontin to be a safe and effective monotherapy.

- **Reflex Sympathetic Dystrophy ("RSD")**: Medical liaisons falsely informed physicians that extensive evidence demonstrated the efficacy of Neurontin in treating RSD. The only such evidence that existed was anecdotal reports of nominal scientific value. Medical liaisons were trained to refer to case reports created or sponsored by Defendants as "studies."

- **Attention Deficit Disorder ("ADD")**: Medical liaisons were instructed to inform pediatricians that Neurontin was an effective treatment of ADD. Only sparse anecdotal evidence supported this claim. Still liaisons reported that many case reports demonstrated the success of treating ADD with Neurontin.

- **Restless Leg Syndrome ("RLS")**: Defendants' medical liaisons were trained to refer to a growing body of data relating to the condition, but no scientific data existed. The only reports were anecdotal, most of which had been created and/or sponsored by Defendants.

- **Trigeminal Neuralgia**: Although medical liaisons represented that Neurontin could treat Trigeminal Neuralgia, again no scientific data supported this claim with the exception of occasional anecdotal reports. No data demonstrated that Neurontin was as effective as other inexpensive pain killers.

- **Essential Tremor Periodic Limb Movement Disorder ("ETPLMD")**: Medical liaisons claimed that Neurontin effectively treated ETPLMD. However, no scientific data supported such claims with the exception of anecdotal reports of nominal scientific value.

- **Migraine Headaches**: Claims that Neurontin effectively treated migraine headaches were purportedly based on early trial results. While pilot studies had been undertaken, no trial results existed at that time. Any data relating to treatment of migraines was purely anecdotal and of nominal scientific value. Most of the case reports were either created or sponsored by Defendants.

- **Drug and Alcohol Withdrawal Seizures**: Medical liaisons misrepresented Neurontin's efficacy for treatment of drug and alcohol withdrawals. No data supported this assertion.

35. Defendants intentionally induced physicians to provide inaccurate medical advice

to their patients regarding the safety and efficacy of Neurontin to treat the above off-label conditions.

Defendants Paid Doctors to Prescribe Neurontin

36. Defendants' illicit marketing strategy employed physicians to promote Neurontin. Defendants made tens of thousands of payments to physicians to act as their surrogate sales force and to prescribe Neurontin themselves.

Consultants Meetings

37. Defendants recruited and paid physicians to attend dinners and conferences where they were encouraged to prescribe Neurontin for unnecessary off-label uses. As part of Defendants' scheme, doctors were told to sign phony consulting agreements and were then compensated as paid consultants to attend the meetings. These "consultants" were not required to provide any *bona fide* services in exchange – the payments were solely to encourage Neurontin prescriptions.

38. A typical "consultants" meeting was held in Jupiter Beach, Florida for neurologists during the weekend of April 19-21, 1996. Defendants' Neurontin Marketing Team targeted neurologists with the greatest potential for increasing Neurontin prescriptions. Thus, sales personnel selected potential attendees from a list of the top-prescribing doctors for anti-epileptic drugs in the Northeast.

39. Qualifying physicians received round-trip airfare to Florida (worth $800), two nights of accommodations (worth $340), free meals and entertainment, ground transportation and a "consultant's fee" of $250. The value of the package was approximately $2,000 per physician.

40. During the Jupiter Beach meeting, Defendants gave presentations relating to Neurontin's off-label uses. The presentations were given under the auspices of an independent company, Proworx. However, all aspects of the presentations were designed, monitored, and

approved by Defendants. The Defendants selected the speakers, picked the topics and previewed the content of the presentations. Defendants paid all the expenses relating to the meeting. Flouting the FDA's prohibition on promotion of off-label uses, Defendants provided written abstracts of the presentations on off-label uses of Neurontin to each of its "consultants."

41. The "consultants" did not provide any professional advice at Jupiter Beach in exchange for the lavish treatment. A later memorandum to Defendants' marketing officials noted that "participants were delivered a hard hitting message about Neurontin" and were encouraged to prescribe Neurontin at higher doses. In addition, Defendants generated "trending worksheets" listing the doctors in attendance. These worksheets enabled Defendants to track attendees' Neurontin prescriptions and determine if they increased their Neurontin prescriptions post-conference.

42. Defendants hosted dozens of similar consultants meetings between late 1995 and 1997, where "consultants" received payments and gratuities along with presentations on off-label Neurontin uses. Comparable meetings included the following destinations: La Costa Resort, Sheraton Grande Torrey Pines and Rancho Bernardo in California; Santa Fe, New Mexico; Marco and Hutchinson Islands, Walt Disney World, Palm Beach and Longboat Key in Florida; the Ritz Carlton in Aspen, Colorado; Southern Pines in North Carolina; the Ritz Carlton in Boston, Massachusetts; Short Hills in New Jersey; and the Ritz Carlton in Atlanta, Georgia. Hundreds, if not thousands, of physicians received financial incentives to attend these events.

Medical Education Seminars

43. Defendants also provided financial incentives for prescribing Neurontin through Continuing Medical Education ("CME") seminars. Such seminars are illegal under marketing restrictions unless they are truly independent of the drug company. For example, a drug company

can make "unrestricted grants" to fund a seminar, but it cannot be involved in formulating the content of the presentations, picking the speakers or selecting the attendees. None of these requirements was observed with regard to CME seminars sponsored by Defendants for the promotion of off-label uses of Neurontin. Although Defendants retained third-party organizations, such as Proworx and MES to present the seminars, Defendants controlled virtually every aspect of these events. Defendants also paid all expenses of the seminar, including the seminar companies' fees.

44. Physicians who wrote a large number of Neurontin prescriptions were compensated comparably to the attendees of the Jupiter Beach consultants meetings. Many physicians received free tuition, free accommodations, free meals, and cash. Further, Defendants' CME seminars were frequently accredited by continuing medical education organizations. Thus, high-volume prescribing physicians could fulfill their continuing medical education licensing requirements by attending Defendants' promotional seminars.

45. Defendants paid extensive incentives to physicians who attended numerous CME seminars conducted by Defendants from 1996 to 1997, including but not limited to, the Merritt-Putnam Epilepsy Postgraduate Course; the Merritt-Putnam Seminar in Chicago, Illinois; New Frontiers in AntiEpileptic Drug Use in California; Diabetic Neuropathy at the Ritz Carlton in Boston, Massachusetts; the Merritt-Putnam Symposium in Key Biscayne, Florida; the Merritt-Putnam Conference on Monotherapy in Palm Springs, California; the Merritt-Putnam Conference on Monotherapy in Saint Louis, Missouri; and the Merritt-Putnam Symposium in Boston, Massachusetts.

Grants and "Studies"

46. Defendants also made outright payments to physicians in the form of grants for

prescribing and advocating Neurontin for off-label uses. Defendants' sales managers identified key doctors who actively prescribed Neurontin and programs that were willing to host Neurontin speakers and encouraged those persons and programs to obtain "educational grants" from Defendants.

47. These grants were charged to Defendants' Neurontin marketing budget. Each grant was made solely because the individual was a large Neurontin supporter and/or would host a program where well-known Neurontin supporters recommended that other physicians increase their prescriptions of the drug. These grants included:

- $2,000 to Berge Ninmpolan, Maryland, "a great Neurontin believer," to attend a neurology seminar in San Francisco, in March 1996;
- $1,000 to the University of Texas at Houston, Department of Neurology, to host a symposium that touted successful "off-label" treatment with Neurontin;
- $3,000 to the University of Texas Medical School to host a conference in August 1996, at which a well-known specialist in epilepsy, who prescribed Neurontin, attended;
- $4,000 to pay for a neurologist from the University of Texas at San Antonio to attend the American Epilepsy Society Conference in December 1996, at which Parke-Davis presented extensive documentation on "off-label" uses for Neurontin;
- $2,500 to the University of Texas at Houston for a seminar facilitated by Dr. B.J. Wilder. Dr. Wilder was one of Neurontin's biggest boosters for "off-label" indications and was paid tens of thousands of dollars to promote Neurontin's "off-label" uses across the country;
- $2,500 in June 1996 to pay for representatives from the University of Pennsylvania Medical Center to attend a conference in Saint Petersburg, Russia, on the utilization of anti-epileptic drugs, including Neurontin;
- $5,000 to Dr. Alan B. Ettinger, of Stony Brook, New York, in December 1996. Dr. Ettinger informed Parke-Davis that he was interested in conducting research on Neurontin, and he maintained a database of patients treated with Neurontin;
- $500 to Bruce Ehrenberg, of Boston, Massachusetts, a leading speaker for Parke-Davis regarding "off-label" uses of Neurontin, to attend a conference in China;

- $1,000 to Israel Abrams, M.D., Paul C. Marshall, M.D., Beth Rosten, M.D. and Spencer G. Weig, of Worcester, Massachusetts, for educational programs in February 1996. According to the local Parke-Davis representative who requested the grant, "much of the Neurontin success in Worcester has been attributed to ... the 4 pedi epileptologists below";

- $1,400 to Dr. Ahmad Beydoun of Ann Arbor, Michigan, for post-graduate training in March 1996. This grant was expedited on the basis that "Dr. Beydoun is a very important customer";

- $1,500 to Jim McAuley, R.Ph., Ph.D., for educational materials relating to epilepsy. Parke-Davis decided to provide the funds because McAuley was an advocate of Neurontin and he was important in getting another Parke-Davis drug, Cerebyx, accepted on the formulary for Ohio State University; and

- A grant in an unknown amount to University Hospital in Cleveland in exchange for hosting programs regarding Neurontin's use in treating neuropathic pain at conferences specifically devoted to obtaining referrals from other doctors.

48. Defendants' medical liaisons informed leading Neurontin prescribers that physicians could receive large grants in exchange for significant advocacy of Neurontin. Often times, participation in a study required little more than collating and writing up office notes or records. Indeed, as discussed above, Defendants frequently hired technical writers to draft the articles for which the "authors" were given grants.

49. Defendants also paid gratuities to physicians to use Neurontin for so-called "studies" that lacked scientific value. Such payments included: $7,000 for Statistical Analysis of Patients Treated with Neurontin for Pain; $7,000 for Reduction of Sympathetically Medicated Pain and Sudomotor Function; $20,000 for Trial of Neurontin for Distal Symmetric Polyneuropathy Associated with AIDS; $25,000 for Neurontin for Neuropathic Pain in Chronic Pain Syndromes; $5,000 for Retrospective Analysis of Neurontin Use with Bipolar Disorder Patients; $2,000 for Retrospective Analysis of Neurontin in the Treatment of Pain; $8,000 for Retrospective Analysis of Neurontin in the Treatment of Chronic Pain; and $4,000 for case histories relating to use of Neurontin as an adjuvant analgesic.

50. By way of illustration, Defendants conducted a study known as STEPS in 1995 and 1996. STEPS was a marketing tool designed to induce neurologists to prescribe Neurontin at far higher doses than indicated in FDA-approved labeling. In contrast to authentic clinical studies, which have a limited number of investigators treating a number of qualified patients, the STEPS trial called for over 1,200 "investigators" to enroll a few patients each. This way Defendants channeled payments to physician "investigators." The participating physicians were instructed to demonstrate that patients could tolerate high dosages of the drug.

51. Physicians enrolling in the STEPS study were paid for both their overall participation in the study and bonuses for every patient they enrolled. Defendants offered the 1,200 investigators additional cash for each patient whose Neurontin prescription continued after the study ended.

Speakers Bureau

52. Defendants also formed a Speakers Bureau as a means to pay physicians for prescribing Neurontin. From 1995 to 2000, the Speakers Bureau sponsored teleconferences, dinner meetings, consultant meetings, educational seminars, and other events to promote off-label uses of Neurontin. The speakers at these events were physicians who were paid from $250 to $3,000 per event to give short presentations relating to Neurontin. Many speakers received tens of thousands of dollars annually to recommend Neurontin to fellow physicians, particularly for off-label uses. The payments far exceeded the fair value of the work, if any, the physicians performed for Defendants.

53. Defendants' marketing personnel, including its medical liaison staff, informed physicians of the lucrative rewards associated with joining the Speakers Bureau. Physicians were informed that if they prescribed enough Neurontin, they could be eligible for substantial payments for describing their clinical experience to peers at events specifically dedicated to the promotion of

off-label uses. Defendants were aware that these payments did not comply with the American Medical Association's guidelines for payments to physicians.

54. In 1997, in the wake of an FDA investigation, Defendants conducted a review of their marketing practices in light of existing federal kickback prohibitions. Defendants determined that none of the programs described herein should have been conducted in the manner that they were conducted. Defendants thereafter issued guidelines essentially prohibiting each of these programs. Nevertheless, Defendants' payments to physicians for off-label uses of Neurontin continued at least until 1998. From Defendants' records, Plaintiff believes that such payments continued through the merger of Parke-Davis's parent, Warner-Lambert, with defendant Pfizer, and through the grand jury investigation into Parke-Davis's marketing practices relating to Neurontin. Plaintiff believes the practice may have even continued through the present.

Defendants' Concealed Use of Ghost-Written Articles to Promote the Off-Label Uses of Neurontin

55. Defendants distributed materials to physicians that concealed their role in the creation and sponsorship of certain publications about Neurontin's benefits and uses. Many of the publications were written by third parties who were retained by Defendants and/or were under Defendants' control.

56. Defendants rewarded doctors for their advocacy of Neurontin by paying an honorarium for lending their names to scientific articles prepared and written by third parties retained by Defendants. For example, in 1996, Defendants retained AMM/Adelphie, Ltd. ("AMM") and MES (collectively "Vendors") to prepare no less than twenty articles for publication in various neurology and psychiatry journals. The authors were fraudulently listed as independent physicians.

57. Once Parke-Davis and its technical writers conceived of the articles, Parke-Davis and outside firms sought recognized Neurontin prescribers to use their names as the authors. In some

cases, a draft article was completed before an "author" was identified. This occurred even in connection with case histories that described the "author's" personal treatment of patients. The physician "authors" were paid an honorarium of $1,000 and were also able to claim publication credit on their *curriculum vitae*.

58. While the article might note that the physician author received an honorarium from an outside firm, the article failed to disclose that Defendants had paid the honorarium or had controlled the content of the articles. For example, an article created by MES, Gabapentin and Lamotrignine, *Novel Treatments for Mood and Anxiety Disorders*, which was published in CNS Spectrums, noted that "an honorarium was received [by the physician 'authors'] from Medical Education Systems for preparation of this article." But, it concealed the fact that Defendants had hired MES to write the article. Similarly, an article widely circulated by Defendants concerning Neurontin's use in the treatment of Restless Leg Syndrome asserted that the authors, Gary A. Mellick and Larry B. Mellick, had not and never would receive financial benefit from anyone with an interest in Neurontin. However, the Mellick brothers received tens of thousands of dollars for acting as speakers at Defendants' events.

59. Defendants used these publications as part of their fraudulent marketing strategy by presenting the articles to physicians as evidence of independent research on Neurontin's efficacy.

60. These non-physician technical writers, physician "authors" and vendors, namely AMM and MES (collectively, the "Promotional Agents"), were key parties in Defendants' improper marketing and sales scheme. They knowingly and willfully facilitated, communicated and distributed misrepresentations concerning the efficacy of Neurontin for off-label uses. Non-physician technical writers wrote articles based on inaccurate, and sometimes nonexistent, scientific evidence. Physicians who lent their names as "authors" to such articles misrepresented the

authorship and objectivity of such articles. In addition, the physicians who performed and participated in sham "studies" regarding the safety and efficacy of Neurontin for off-label uses knowingly misrepresented facts and evidence concerning Neurontin's off-label uses. The Vendors caused the articles to be published in a variety of medical journals across the country.

61. The Promotional Agents were aware of, and interacted with, other participants in the fraudulent scheme.

62. The Promotional Agents operated collectively for a common purpose and as a continuing unit to perpetrate the fraudulent scheme relating to Neurontin.

63. The Promotional Agents' collective knowledge, involvement and activity is evidenced in part by:

- Their failure to advise government regulators (including Medicaid), private insurers, third-party payors and patients of the existence and spread of such misinformation concerning off-label uses of Neurontin;
- Their acceptance of various types of incentives from Defendants to write, author and have published articles containing misrepresentations regarding the off-label uses of Neurontin with the knowledge that other physicians, and third-party payors, would rely on such information; and
- Their agreement to permit Defendants to control the information relayed to the public in such articles.

DEFENDANTS' MOTIVE

64. Defendants' motive to create and operate the deceptive scheme described herein was additional sales and revenues from Neurontin for non-FDA-approved, off-label use.

65. The deceptive scheme was designed to, and did, cause Plaintiff and the Classes (as defined below) to pay for treatment with Neurontin of conditions for which the drug is not medically necessary, safe, or efficacious. The deceptive scheme also caused Plaintiff and the Classes to pay for Neurontin to treat non-FDA approved conditions. In the absence of Defendants' deceptive

conduct, Plaintiff and the Classes would not have paid for these pharmaceuticals.

CLASS ALLEGATIONS

66. Under Rule 23 of the Tennessee Rules of Civil Procedure, Plaintiff brings this action on behalf of himself and the Class defined as follows:

> All persons who directly paid for prescriptions and/or indications of Neurontin, paid deductibles, or paid any out-of-pocket expenses for prescriptions for off-label, non-FDA approved conditions and/or not medically necessary, safe, or efficacious treatment during the period from October 29, 1999 through the present.

Excluded from the Class are (a) Defendants and any entity in which any Defendant has or had a controlling interest, and their legal representatives, officers, directors, assigns and successors, and (b) any co-conspirators.

67. The Class consists of innumerable individuals and entities throughout Tennessee, making individual joinder impracticable. The disposition of the claims in a single class action will provide substantial benefits to all parties, promote judicial efficiency and economy and allow for trial of this matter on behalf of the Class in a single forum.

68. Plaintiff's claims are typical of the claims of the Class, in that Plaintiff, like all members of the Class, paid for off-label use prescriptions not approved by the FDA, and paid for prescription for conditions which the drug is not medically safe and/or efficacious. Plaintiff, like all members of the Class, has been damaged by Defendants' misconduct, in that he paid for Neurontin to treat conditions for which the FDA has not approved it and/or it is not medically effective or safe.

69. The factual and legal bases of Defendants' misconduct is common to all members of the Class and represents a scheme and common course of deception and other misconduct resulting in injury to Plaintiff and all members of the Class.

70. Common questions of law and fact predominate over any questions that may affect individual members of the Class and include, but are not limited to, the following:

A. Whether Defendants engaged in a fraudulent and/or deceptive scheme of improperly marketing and selling Neurontin for treating conditions for which it is not safe or medically necessary or efficacious, off-label and/or for which Neurontin was not FDA approved;

B. Whether Defendants engaged in a pattern and practice that directly caused Plaintiff and members of the Class to pay for Neurontin prescriptions for non-medically approved, unnecessary, unsafe, non-efficacious or inappropriate uses;

C. Whether Defendants coached and/or instructed physicians how to conceal the off-label nature of Neurontin prescriptions to Plaintiff and members of the Class;

D. Whether it was the policy and practice of Defendants to prepare, fund and publish materials that contained false information and misrepresentations regarding off-label uses for Neurontin;

E. Whether Defendants paid non-physician technical writers to write articles containing misinformation and misrepresentations concerning purported scientific evidence regarding the safety and medical efficacy of Neurontin to treat off-label conditions;

F. Whether Defendants paid physicians to "author" articles written by others containing misinformation and misrepresentations concerning purported scientific evidence to support the use of Neurontin for the treatment of conditions for which it has not been scientifically proven to be safe or medically effective;

G. Whether Defendants paid Vendors, namely AMM and MES, to market articles containing misinformation and misrepresentations concerning purported scientific evidence regarding off-label uses of Neurontin for which the drug is not safe or medically necessary;

H. Whether Defendants are liable to the members of the Class for damages for conduct that is actionable under the Tennessee Consumer Protection Act, § 47-18-101, *et seq.*;

I. Whether Defendants unjustly enriched themselves at the expense of members of the Class.

J. Whether Defendants are liable for breach of the implied warranty of merchantability.

K. Whether Defendants are liable for breach of the implied warranty of fitness for a particular purpose.

71. Plaintiff will fairly and adequately represent and protect the interests of the Class, and has retained counsel with substantial experience in prosecuting class actions. Plaintiff and counsel are committed to vigorously prosecuting this action on behalf of the Class, and have the financial resource to do so. Neither Plaintiff nor its counsel has any interest adverse to that of the Class.

72. Plaintiff and members of the Class have suffered, and will continue to suffer, harm and damages as a result of Defendants' unlawful conduct.

73. A class action is superior to other available methods for the fair and efficient adjudication of the controversy. Absent a class action, most members of the Class likely would find the cost of litigating their claims to be prohibitive, and will have no effective legal remedy. The class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation because it will conserve judicial resources and promote consistency and efficiency. Defendants have acted and failed to act on grounds generally applicable to Plaintiff and the Class, requiring Court imposition of uniform relief to ensure compatible standards of conduct toward the Class.

TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

74. Any applicable statute of limitations has been tolled by Defendants' intentional concealment of the facts alleged herein. Defendants concealed from Plaintiff and members of the Class vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part.

75. In May 2004, news media reported that Defendants had entered into a criminal plea agreement with the federal government, and a civil settlement agreement with the attorneys general of different states, in which defendants admitted the wrongdoing described herein. A *qui tam* action which was filed in the U.S. District Court for the District of Massachusetts came to light only recently because it was filed under seal.

76. Plaintiff and members of the Class, in the exercise of reasonable diligence, could not have discovered Defendants' wrongdoing before this announcement. Many members of the Class may still be unaware of Defendants' wrongdoing. Accordingly, Defendants are estopped from relying on any statute of limitations.

77. Because of Defendants' intentional concealment of the acts and practices that gave rise to Plaintiff's claims, Plaintiff asserts the tolling of any applicable statutes of limitations that may affect its claims.

COUNT I

Violations of the Tennessee Consumer Protection Act, § 47-18-101, *et seq.*

78. Plaintiff repeats and incorporates by reference the allegations contained in the paragraphs above, as if fully set forth herein.

79. This cause of action arises under the Tennessee Consumer Protection Act, § 47-18-101, *et seq.*, and is brought on behalf of Plaintiff and all similarly situated members of the Class.

80. Tennessee Consumer Protection Act, § 47-18-104 provides, in relevant part:

> Deceptive and unconscionable trade practices made unlawful and prohibited by this Chapter include but are not limited to, the following:
>
> (b) Without limiting the scope of subsection (a), the following unfair or deceptive acts or practices affecting the conduct of any trade or commerce are declared to be unlawful and in violation of this part:
>
> (2) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services. This subdivision (b)(2) does not prohibit the private labeling of goods and services;
>
> (5) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship approval, status, affiliation or connection that such person does not have; and
>
> (27) Engaging in any other act or practice which is deceptive to the consumer or to any other person;

81. Plaintiff was prescribed Neurontin for nerve damage resulting from a neck operation in approximately March 2004.

82. The actions, and failures to act, of Defendants, including the false and misleading representations and omissions of material facts regarding the off-label uses for Neurontin and the above described course of deceptive conduct and deceptive concealment, constitute unconscionable commercial practices, deception, false pretenses, misrepresentations, and the knowing concealment, suppression or omission of material facts with the intent to induce reliance in violation of T.C.A.. § 47-18-101, *et seq*.

83. As a direct and proximate result of Defendants' acts and omissions, Plaintiff and members of the Class have suffered losses through payments, deductibles, and other out-of-pocket expenses for Neurontin prescriptions for off-label, non-FDA approved and/or medically unnecessary uses.

84. Physicians relied upon Defendants' misrepresentations and omissions in prescribing Neurontin for "off-label" uses. Plaintiff and the Class were damaged by paying for these

prescriptions.

85. Under T.C.A. § 47-18-101, *et seq.*, Plaintiff and members of the Class are entitled to actual damages sustained as a result of Defendants' misconduct, attorneys' fees and costs of bringing this suit, in addition to any other appropriate legal or equitable relief. In addition, because Defendants' violations were intentional, the damages to the Plaintiff and other members of the Class should be trebled.

COUNT II

Unjust Enrichment

86. Plaintiff repeats and incorporates by reference the allegations contained in the paragraphs above, as if fully set forth herein.

87. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefitted from the payment for Neurontin by Plaintiff and members of the Class to treat off-label conditions for which the drug is not FDA-approved and/or is not medically necessary.

88. Defendants have knowingly received, and continue to receive, a substantial benefit at the expense of Plaintiff and members of the Class.

89. It would be unjust and unconscionable to permit Defendants to enrich themselves at the expense of Plaintiff and members of the Class and to retain the funds wrongfully obtained from the Class.

COUNT III

Breach of Implied Warranty of Merchantability

90. Plaintiff repeats and incorporates by reference the allegations contained in the paragraphs above, as if fully set forth herein.

91. Defendants, in the manufacture, marketing and/or sale of Neurontin, impliedly

warranted to Plaintiff and Class members that Neurontin was fit for the ordinary purpose for which Neurontin was prescribed.

92. Neurontin is a prescription drug approved only for the treatment of partial seizures associated with epilepsy (as adjunctive therapy), and the management of post-herpetic neuralgia. It is not approved for the uses for which it was promoted and sold to Plaintiff and the Class members. Accordingly, Neurontin is not suitable for the purpose for which it was marketed and promoted to Plaintiff and the Class members, and was not merchantable. Defendants have breached the implied warranty of merchantability. Neurontin is not reasonably fit for the specific off-label purposes for which Defendants knowingly sold it and for which the Plaintiff and Class members bought Neurontin in reliance on Defendants.

93. As a direct and proximate result of Defendants' conduct, Plaintiff and the Class members have suffered actual and other damages.

COUNT IV

Breach of Implied Warranty of Fitness for a Particular Purpose

94. Plaintiff repeats and incorporates by reference the allegations contained in the above paragraphs, as if fully set forth herein.

95. Defendants, in the manufacture, marketing and/or sale of Neurontin, impliedly warranted to Plaintiff and the Class members that Neurontin was fit for a particular purpose.

96. Defendants had reason to know that Plaintiff and the Class members were relying on Defendants' skill and judgment in order to select or furnish suitable goods for Plaintiff's and the Class members' particular purpose.

97. Neurontin is not approved for the uses for which it was promoted and sold to the Plaintiff and the Class members. Accordingly, Neurontin is not suitable for the purpose for which

it was marketed and promoted to the Plaintiff and Class members. Defendants have breached the implied warranty of fitness for a particular purpose. Neurontin is not reasonably fit for the specific off-label purpose for which Defendants knowingly sold it and for which the Plaintiff and Class members bought Neurontin in reliance on Defendants.

98. In fact, no evidence had been legally established at the time which justified the promotion of Neurontin for unapproved uses, and this was known to Defendants.

99. As a direct and proximate result of Defendants' conduct, the Plaintiff and Class members have suffered actual and other damages.

DEMAND FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants in each claim for relief, jointly and severally, as follows:

A. Plaintiff, on behalf of himself and all Class members prays for an Order certifying that this action may be maintained as a class action, appointing Plaintiff and his counsel to represent the Class, and directing that reasonable notice of this action be given by the Defendants to Class members;

B. On Plaintiff's claims under the Tennessee Consumer Protection Act and Breach of Implied Warranties, Plaintiff prays for recovery of compensatory damages, plus Plaintiff's costs in this suit, including reasonable attorneys' fees. In addition, because Defendants' violations were intentional, the damages to the Plaintiff and other members of the Class should be trebled;

C. On Plaintiff's claims for unjust enrichment, Plaintiff prays for recovery in the amount of payments, deductibles, and other out-of-pocket expenses for Neurontin treatment of non-FDA approved and/or medically unnecessary, safe, or efficacious uses, as determined at trial, plus

Plaintiff's costs in this suit, including attorneys' fees;

D. Plaintiff prays for an order freezing Defendants' assets, and requiring Defendants to pay restitution to Plaintiff, all members of the Class and the general public and to restore to the public all funds acquired by means of any act or practice declared by this Court to be unlawful, deceptive, fraudulent or unfair, and/or a violation of laws, statutes or regulations;

E. Award Plaintiff and members of the Class other appropriate equitable relief;

F. Award Plaintiff its costs and expenses in this litigation, including reasonable attorneys' fees and expert fees; and

G. Award Plaintiff and members of the Class such other and further relief as may be just and proper under the circumstances.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Respectfully submitted,

GLASSMAN, EDWARDS, WADE & WYATT, P.C.

By: _____

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File # 04-638WK

05-2113-Ma An

JS 44 (Rev. 3/99)

CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS
Donald Miller, On Behalf of himself and Others Similarly Situated

(b) County of Residence of First Listed Plaintiff Shelby
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS Pfizer, Inc., Warner Lamber Company, LLC and Parke-Davis, & Company, a Division of Warner-Lambert Company

County of Residence of First Listed Shelby
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

(c) Attorney's (Firm Name, Address, and Telephone Number)
B.J.Wade & Russell A.Wood
Glassman,Edwards,Wade&Wyatt P.C.
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901-527-4673

Attorneys (If Known)
Prince C. Chambliss, Jr.
Stokes Bartholomew Evans & Petree, P.A
1000 Ridgeway Loop Road, Suite 200
Memphis, TN 38103 901-525-6781

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

		DEF			DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury—Med. Malpractice
- ☐ 365 Personal Injury — Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900 Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes
- ☒ 890 Other Statutory Actions

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence
- Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

V. ORIGIN (PLACE AN "X" IN ONE BOX ONLY)

☐ 1 Original Proceeding ☒ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write brief statement of cause. Do not cite jurisdictional statutes unless diversity.)

Removal from State Court

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 (See instructions): **DEMAND $**

CHECK YES only if demanded in complaint: **JURY DEMAND:** ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY JUDGE _____ DOCKET NUMBER _____

DATE February 8, 2005

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUN _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____